

Appl. No. : 10/771,845  
Filed : February 4, 2004

## REMARKS

By way of summary, prior to this Amendment Claims 1-16 were pending in this application. Although the Office Action Summary and the Office Action recognition of the Election/Restrictions at Office Action p. 2 state that Claims 1-17 were elected and are pending, Applicant's January 4, 2007 election was for Claims 1-16. Claims 1, 10, 11, 12, 13, 15 and 16 have been amended, Claim 48 has been added, and Claims 8, 9 and 14 have been cancelled.

In the outstanding Office Action of March 8, 2007, the Examiner rejected Claim 13 under 35 U.S.C. §112, rejected Claims 1, 4, 7, 9, 10, 11, 13, 15 and 16 under 35 U.S.C. §102(b) as being anticipated by Koike et al. (U.S. 6,221,092), rejected Claims 1-5, 7, 9, 10, 13 and 15 under 35 U.S.C. §102(e) as being anticipated by Peavey et al. (U.S. Pub. 2003/0225421), and rejected Claims 1 and 6 under 35 U.S.C. §102(e) as being anticipated by Ryan et al. (U.S. Pub. 2003/0191495). The Examiner also rejected Claim 11 under 35 U.S.C. §103(a) as being unpatentable over Peavey in view of Neuss (U.S. 6,355,052), Claims 8 and 14 under 35 U.S.C. §103(a) as being unpatentable over Koike in view of Wahr et al. (U.S. 2002/0183787), and Claim 12 under 35 U.S.C. §103(a) as being unpatentable over Koike in view of Heuebsch et al. (U.S. 6,312,446).

### **I. Claim Amendments**

In this Amendment, Claims 1, 10 and 13 have been amended to further define the subject matter for which protection is sought and to expedite issuance of a patent. Claim 48 has been added by this Amendment. Applicant respectfully submits that the added claim reads upon the previously elected species of active expanders without introducing any new matter.

The Applicant respectfully submits that the claims as previously pending are patentably distinguished over the cited references or any combination thereof. However, to expedite prosecution, Applicant has amended the claims in order to clarify the features of Applicant's claimed invention. Applicant reserves the right to pursue the previously unamended claims or claims of broader scope at a later date.

### **II. § 112 Claim Rejection**

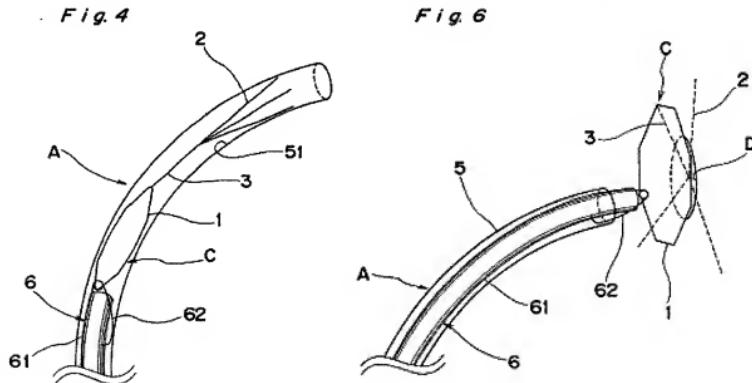
In the outstanding Office Action of March 8, 2007, the Examiner rejected Claim 13 under 35 U.S.C. §112. Claim 13 has been amended as indicated above to recite "positioning a

catheter." Therefore, Applicant respectfully requests the Examiner to withdraw the rejection of Claim 13 under 35 U.S.C. §112.

### III. § 102(a) Claim Rejections

#### A. Amended Independent Claims 1 and 10 are not anticipated nor rendered obvious by Koike

In the outstanding Office Action of March 8, 2007, the Examiner rejected Claims 1, 4, 7, 9, 10, 11, 13, 15 and 16 under 35 U.S.C. §102(b) as being anticipated by Koike et al. (U.S. 6,221,092). Koike discloses a closure device directed to open holes in the septa with a disk-shaped proximal closure member 1 and an elastic distal fixing member 2 connected by a single intermediate elastic member 3. As the Examiner states at page 10 of the Office Action, Koike fails to teach locking the device in position after deployment.



Unlike the methods recited in Claims 1 and 10, Koike does not teach or suggest a method of closing a patent foramen ovale (PFO). In fact, nowhere does Koike mention closure of a patent foramen ovale, which is a natural structure located between the atria. Koike discloses particular examples relating the Koike invention to ventricular septal defects (Koike col. 1, line 9) and describes Fontan operations for ventricular anomalies, such as a single ventricle (Koike col. 1, line 12) and operative procedures creating a Fontan fenestration in response to ventricular

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defects by surgically creating open holes in the atria (Koike col. 1, ll. 10-37). Koike then distinguishes its invention from atrial septal defect devices (Koike col. 1, line 38 – col. 2, line 25) as means for closing holes in the heart created during the creation of a Fontan fenestration. The PFO is not a simple hole in the heart surgically created during a procedure for treating ventricular defects.

Moreover, independent Claims 1 and 10 have been amended in order to clarify certain features of Applicant's claimed invention. In particular, amended independent Claim 1 recites, in part, "wherein the device is self-expandable to a deployment shape wherein the proximal, intermediate and distal segments are generally parallel to one another." Further, amended Claim 1 now includes a limitation previously presented in cancelled Claim 8. Amended independent Claim 1 recites, in part, "locking the position of the closure device after deployment." Amended Claim 10 now includes a limitation previously presented in cancelled Claim 14. Amended independent Claim 10 recites, in part, "locking the device in its clip configuration after deployment." Koike fails to teach locking the device in position after deployment. Office Action p. 10. Claims 8 and 14 were not rejected by the Examiner as being anticipated, or rendered obvious, by Koike alone. Therefore, Applicant respectfully submits that the rejection of independent Claims 1 and 10, which now include the further limitations from Claim 8 and 14, be withdrawn. Applicant will address the Examiner's obviousness rejection of Claims 8 and 14 over Koike and Wahr below.

Dependent Claims 4, 7, 11, 13 15 and 16 depend from amended Claims 1 and 10 and further define the invention of Claims 1 and 10. Claim 9 has been cancelled. For at least the reasons set forth above with respect to Claims 1 and 10, Applicant respectfully submit that Claims 4, 7, 11, 13 15 and 16 are not anticipated nor rendered obvious over Koike. Claims 4, 7, 11, 13 15 and 16 are also patentable over Koike in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 1, 4, 7, 10, 11, 13, 15 and 16 based on Koike.

**B. Amended Claims 1 and 10, like cancelled Claims 8 and 14, are not rendered obvious by Koike in view of Wahr et al. (U.S. 2002/0183787);**

In the outstanding Office Action of March 8, 2007, the Examiner rejected Claims 8 and 14 under 35 U.S.C. §103(a) as being unpatentable over Koike in view of Wahr et al. (U.S.

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2002/0183787). Although Claims 8 and 14 have been cancelled, language of Claim 8 has been incorporated into amended Claim 1 and language of Claim 14 has been incorporated into amended Claim 10. Applicant asserts that one skilled in the art would not have found a reason to combine Koike with Wahr, and that the Examiner has not explicitly articulated any reason why one skilled in the art would have combined the prior art elements in the manner claimed by the Applicant.

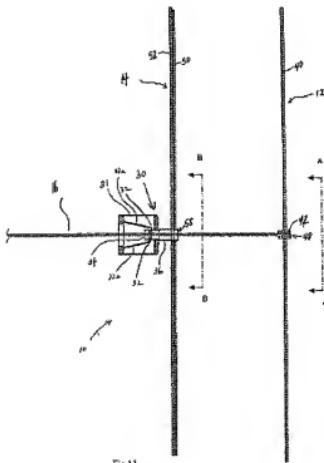
The Supreme Court's decision on *KSR Int'l. v. Teleflex, Inc.* refines the issue of obviousness under 35 U.S.C. §103(a) in relation to prior art. *KSR Int'l. v. Teleflex, Inc.*, No 04-1350 (U.S. Apr. 30, 2007). The Court noted that the analysis supporting a rejection under 35 U.S.C. §103(a) should be made explicit, and that it was "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements: in the manner claimed. The Court specifically stated:

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an **apparent reason** to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis **should be made explicit**. *See In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness").

*KSR*, slip op. at 14 (emphasis added). Therefore, in making a rejection under 35 U.S.C. §103(a) based upon a combination of prior art elements, Applicant submits that the Examiner must expressly identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. Beyond the conclusory statements made in the Office Action, the Examiner has failed to do so.

Applicant further submits that one skilled in the art would not look to Wahr to modify an open septal defect method as in Koike, because Koike does not teach a use specific to the PFO as discussed above. Moreover, amended independent Claim 1 recites, in part, that "the device is self-expandable to a deployment shape wherein the proximal, intermediate and distal segments are generally parallel to one another." As shown below in Wahr Fig. 11, an intermediate portion

of Wahr includes a single elongate tether 16 that is generally perpendicular to both the proximal 14 and distal 12 segments:



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First, in the I-shaped configuration disclosed in Wahr, the proximal 14, intermediate 16 and distal 12 segments are not generally parallel to one another. Second, the tether 16 in Wahr is flexible and non-biased, thus the Wahr device is not self-expandable. In order to actuate the Wahr device into its deployed configuration the surgeon must either pull the tether 16 proximally with respect to the proximal segment 14 or push the proximal segment 14 with respect to the tether 16 in order to lock the proximal segment 14 using the locking mechanism disclosed in Wahr. One skilled in the art would have not have combined the Koike and Wahr elements in the manner claimed by the Applicant in Claim 1 for at least the reason that the flexible tether/rip cord actuation structure would not be used in the device taught in Koike. The Koike intermediate segment 3 is made of a biased elastic member which does not require the manual manipulation of Wahr to enter its deployed configuration. The biased Koike "elastic member 3 is made of an easily inflective elastic material similar to those used for the frame 12" which returns to its "original condition" once it is removed from the catheter. Koike col. 4, ll. 29-36.

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In contrast to the disclosure and teachings of Koike and Wahr, amended independent Claim 10 recites, in part, “when the device is in its clip configuration the device has generally an S-shape.” As shown above the Koike device’s proximal segment 1 connects to the top of intermediate segment 3, which then extends to the center of distal segment 2 instead of extending to the bottom of distal segment 2. Thus, the Koike device does not have a generally S-shape. As shown above in Wahr Fig. 11, Wahr has an I-shape and does not disclose that its device “has generally an S-shape” as required by Applicant’s Claim 10. Therefore, the Examiner has not articulated any proposed combination of the references that satisfies the limitations of Claim 10.

For at least the reasons set forth above with respect to Claim 1 and to Claim 14, as well as the lack of an explicit reason to combine Koike in view of Wahr, Applicant respectfully submits that amended Claims 1 and 10 are patentable over Koike in view of Wahr. Therefore, Applicant respectfully requests the Examiner to withdraw any potential rejection of Claims 1 and 10 based on Koike in view of Wahr.

**C. Amended Independent Claims 1 and 10 are not anticipated nor rendered obvious by Peavey**

In the outstanding Office Action of March 8, 2007, the Examiner rejected Claims 1-5, 7, 9, 10, 13 and 15 under 35 U.S.C. §102(e) as being anticipated by Peavey et al. (U.S. Pub. 2003/0225421). As discussed above, amended Claim 1 now incorporates additional limitations from former Claim 8 and amended Claim 10 now incorporates additional limitations from former Claim 14. Since Claim 8 and Claim 14 were not rejected by the Examiner in the Office Action in light of Peavey, Applicant requests that the Examiner reconsider and withdraw the rejection of amended independent Claims 1 and 10 based on Peavey.

Dependent Claims 2-5, 7, 13 and 15 depend from amended Claims 1 and 10 and further define the invention of Claims 1 and 10. For at least the reasons set forth above with respect to Claims 1 and 10, Applicant respectfully submit that Claims 2-5, 7, 13 and 15 are not anticipated nor rendered obvious over Peavey. Claims 2-5, 7, 13 and 15 are also patentable over Peavey in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 1-5, 7, 10, 13 and 15 based on Peavey.

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**D. Amended Independent Claim 1 is not anticipated nor rendered obvious by Ryan**

In the outstanding Office Action of March 8, 2007, the Examiner rejected Claims 1 and 6 under 35 U.S.C. §102(e) as being anticipated by Ryan et al. (U.S. Pub. 2003/0191495). As discussed above, amended Claim 1 now incorporates additional limitations from former Claim 8. Since Claim 8 was not rejected by the Examiner in the Office Action in view of Ryan, Applicant requests that the Examiner reconsider and withdraw the rejection of amended independent Claim 1 based on Ryan.

Dependent Claim 6 depends from amended Claims 1 and further defines the invention of Claim 1. For at least the reasons set forth above with respect to Claim 1, Applicant respectfully submit that Claim 6 is not anticipated nor rendered obvious over Ryan. Claim 6 is also patentable over Peavey in view of the additional limitations recited that claim. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 1 and 6 based on Peavey.

**IV. § 103(a) Claim Rejections**

**A. Claim 11 is not rendered obvious by Peavey in view of Neuss (U.S. 6,355,052);**

In the outstanding Office Action of March 8, 2007, the Examiner rejected Claim 11 under 35 U.S.C. §103(a) as being unpatentable over Peavey in view of Neuss (U.S. 6,355,052). Dependent Claim 11 depends from amended Claim 10 and further defines the invention of Claim 10. For at least the reasons set forth above with respect to Claim 10, Applicant respectfully submit that Claim 11 is patentable over Peavey in view of Neuss. Claim 11 is also patentable over Peavey in view of Neuss in view of the additional limitations recited in its claim. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claim 11 based on Peavey in view of Neuss.

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**B. Claim 12 is not rendered obvious by Koike in view of Heuebsch et al. (U.S. 6,312,446);**

In the outstanding Office Action of March 8, 2007, the Examiner rejected Claim 12 under 35 U.S.C. §103(a) as being unpatentable over Koike in view of Heuebsch et al. (U.S. 6,312,446). Dependent Claim 12 depends from amended Claim 10 and further defines the invention of Claim 10. For at least the reasons set forth above with respect to Claim 10, Applicant respectfully submit that Claim 12 is patentable over Koike in view of Heuebsch. Claim 12 is also patentable over Koike in view of Heuebsch in view of the additional limitations recited in its claim. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claim 12 based on Koike in view of Heuebsch.

**V. Conclusion**

Applicant respectfully submits that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or prior art, the Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Applicant respectfully requests that a Notice of Allowance be issued at the earliest opportunity. However, if the Examiner has any questions or concerns, the Examiner is invited to

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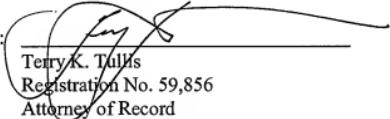
telephone Applicant's attorney of record so that extended prosecution of this application may be avoided.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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